



MAY 8 2001

NADA 140-971

Rosalind S. Dunn  
Associate Director  
Regulatory Affairs, Support and Liaison  
Merial Ltd.  
3239 Satellite Boulevard  
Building 500  
Duluth, GA 30096-4640

Dear Ms. Dunn:

We have become aware of two items used to promote your prescription drug product Heartgard® Plus (ivermectin/pyrantel), NADA 140-971, which are in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Specifically, we refer to the labeling piece "ZOONOTIC PARASITES" (item number HGD-9-1002.1.76-FDP), and the print advertisement "RELIABLE Protection" (item number HGD-0-1002.1.77-TVJ).

Item HGD-9-1002.1.76-FDP presents a table comparing the efficacy of Heartgard Plus (HG), milbemycin oxime products (MBO), and selamectin for the "*treatment and control*" of six canine parasites that have zoonotic potential. We recognize that HG is approved for the "treatment and control" of *Ancylostoma caninum*; we also recognize that MBO is approved for the "control" of *A. caninum*. However, this promotional item may leave some readers with the impression that MBO has no effect on *A. caninum*, which may be misleading. Thus, the presentation calls into question the efficacy of MBO. A sponsor misbrands its own drug product by making false or misleading representations about another product in its labeling.

Items HGD-9-1002.1.76-FDP and HGD-0-1002.1.77-TVJ lack fair balance. Item HGD-9-1002.1.76-FDP uses the statement "HEARTGARD Plus is labeled to treat & control MORE species of the canine parasites implicated in zoonoses than any other product of its kind." Item HGD-0-1002.1.77-TVJ uses the statements "HEARTGARD Plus is 100% effective against..." and "Choose HEARTGARD Plus *for protection that's reliable, convenient and guaranteed\**." The package insert for this product includes the precaution that "All dogs should be tested for existing heartworm infection before starting treatment with HEARTGARD® Plus which is not effective against adult *D. immitis*." and reported side effects include mydriasis, ataxia, staggering and convulsions. Promotional labeling and advertisements that fail to present the risks associated with the use of a drug in the same scope, depth, or detail as the benefits in their body lack fair balance.

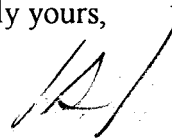
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We ask that you immediately discontinue dissemination of the promotional material cited in this letter, and any other similar ones intended for future dissemination. Please inform us of your intentions as soon as possible but not later than 30 days following receipt of this letter.

If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'V. Vengris', with a large, sweeping flourish extending from the end of the signature.

Vitolis Vengris, D.V.M., Ph.D.  
Team Leader, Marketed Products  
Scientific and Regulatory Review Team  
Division of Surveillance  
Center for Veterinary Medicine